Chemical Right-to Know Program Ethyl Cyanaocrylate (CAS 7085-85-0) Registration Number

# **TEST PLAN (Modified July 2003)**

# Ethyl Cyanoacrylate CAS No. 7085-85-0

STUDY	INFORMATION (Y/N)	OECD Study	GLP	ACCEPTABLE (Y/N)	SIDS TESTING REQUIRED (Y/N)
Physical/Chemical Elements					
Melting Point	Yes	Unknown	Unknown	Yes	No
Boiling Point	Yes	Unknown	Unknown	No	Yes
Vapor Pressure	Yes	Unknown	Unknown	No	Yes
Partition Coefficient	Yes	Yes	Yes	Yes	No
Water Solubility	Yes	Yes	Yes	Yes	No
Environmental Fate and Pathways Elements					
Photodegradation	Yes	N/A	N/A	No	No <sup>1</sup>
Stability in Water	Yes	Yes	Yes	Yes	No
Biodegradation	Yes	N/A	N/A	Yes	No
Fugacity	Yes	N/A	N/A	Yes	No
Ecotoxicity Elements					
Acute Fish	Yes	N/A	N/A	Yes	No
Toxicity to Aquatic Plants	Yes	N/A	N/A	Yes	No
Acute Toxicity to Aquatic Invertebrates	Yes	N/A	N/A	Yes	No
Health Elements					
Acute Toxicity	Yes	Equivalent	No	Yes	No
Genetic Tox. in vivo)	Yes	Unknown	Unknown	Yes	No
Genetic Tox. in vitro)	Yes	Unknown	Unknown	Yes	No
Repeat Dose Toxicity	Yes	N/A	N/A	Yes	No
Reproductive Toxicity	Yes	N/A	N/A	Yes	No
Developmental Tox.	Yes	N/A	N/A	Yes	No

 $<sup>^{\</sup>rm 1}$  Upon receipt of Vapor pressure and Boiling point test results Henkel Loctite will perform AOPWIN modeling as suggested by EPA.

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#### **JUSTIFICATION**

**Physical and Chemical Elements** 

The melting point of ethyl cyanoacrylate is documented in standard adhesive textbooks. This data is considered adequate and no further testing is proposed. The boiling point and vapors pressure will be determined by OECD method TG103 and TG 104 as suggested by the EPA in their comments to Henkel Loctite's original submission. Testing to determine the partition coefficient failed to produce a value because of the reactive nature of the monomer.

#### **Environmental Fate and Pathway Elements**

Alkyl cyanoacrylates are among the most reactive monomers known in anionic polymerization. In the atmosphere and in biological systems, the available hydroxyl ions initiate rapid polymerization as evidenced by the rapid bonding to skin by instant adhesives comprising predominantly cyanoacrylate esters. This property renders ethyl cyanoacrylate a useful adhesive and makes significant exposure to ethyl cyanoacrylate monomer improbable.

The risk of either environmental or biological exposure is further reduced by the manufacture, distribution, and use patterns. Ethyl cyanoacrylate is produced in closed systems and held at the manufacturing site in 55-gallon drums. After it is formulated for commerce, the predominant product size is less than one ounce. The product is used either drop-wise or as a small bead. Thus, an accidental discharge during distribution and use would be limited in size, and therefore neither environmental modeling nor testing is warranted. However as suggested by the EPA, Loctite plans to conduct AOPWIN modeling for photodegradation upon completion of the boiling point and vapor pressure determination discussed above.

### **Ecotoxicity Elements**

For the reasons described in the previous section, the risk exposure of aquatic organisms is extremely limited. Furthermore testing in aquatic animals is not feasible. As detailed in the section on health effects, The National Toxicology Program (NTP) had difficulty in implementing a delivery system for dosing terrestrial animals and recommended that ethyl cyanoacrylate be removed from their priority testing list<sup>1</sup>. We therefore conclude no value would be derived from attempting to test ethyl cyanaocrylate in aquatic organisms.

## **Health Elements**

Data is provided for acute oral and acute dermal toxicity, eye and skin irritation, and acute inhalation toxicity. No additional testing is planned. This is consistent with the position of the Environmental Defense Fund, which on its scorecard has recorded that there is adequate acute toxicity information for ethyl cyanoacrylate.

Reported<sup>2</sup> workplace exposure levels are up to 0.21 ppm for a 40-minute exposure, and an 8-hour time weighted average (TWA) of 0.06 ppm during the manufacture of ethyl cyanoacrylate. The maximum level reported when ethyl cyanoacrylate adhesive was used in a manufacturing process was 0.21ppm for an 8 hour TWA. Levels found in the Loctite manufacturing plant<sup>3</sup> ranged from 0.003 to 1.5 ppm for exposures of 15 minutes or less. Eight-hour time weighted averages were nearly always below 0.1 ppm. The American Conference of Governmental Industrial Hygienists (ACGIH) has established a TLV of 0.2 ppm (8-hour TWA) for ethyl cyanoacrylate. ACGIH has not suggested a short-term exposure limit or a ceiling value for ethyl cyanoacrylate.

<sup>1 60</sup> FR 42987, 1995.

<sup>&</sup>lt;sup>2</sup> Methyl cyanoacrylate and ethyl cyanoacrylate, Risk assessment document, UK Health and Safety Executive

HMSO, Norwich UK, 2000.

<sup>&</sup>lt;sup>3</sup> Paustenbach, D., et al, Am. Ind. Hyg. Assoc J., <u>62</u>, 70-79, 2001.

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Monomeric ethyl cyanoacrylate has an unpleasant acrid odor and is irritating to the eyes and mucous membranes of the nose, throat, and upper respiratory tract. The odor threshold is reported as 1 ppm and the irritation threshold 3-5 ppm<sup>4</sup>. These properties make even occasional exposures to toxic levels of ethyl cyanoacrylate improbable as discomfort propels one to leave any area where the airborne concentration of cyanoacrylate is appreciably above the irritation threshold.

The NTP has completed in-vivo and in-vitro genetic toxicity tests. No further testing in these categories is necessary.

As would be anticipated from this chemistry, dosing animals for repeated dose studies is problematic. Ethyl cyanoacrylate was listed by the Interagency Test Committee as a TSCA 4(e) priority chemical. After preliminary work, NTP<sup>5</sup> recommended its removal from the priority list citing "high reactivity of the chemical and the resulting difficulties in implementing the delivery of an effective concentration of the un-polymerized chemical to the test animals". NTP<sup>6</sup> also reported that they were unable generate a stable aerosol.

The United Kingdom Health and Safety Executive (HSE) has published a Risk Assessment Document on methyl and ethyl cyanoacrylate<sup>7</sup>. This risk assessment concluded that there are no grounds for concern of carcinogenicity at exposures below the threshold for chronic inflammatory responses in tissues at the site of contact. In addressing reproductive toxicity, HSE concluded "due to the reactive nature of ethyl cyanoacrylate, little systemic distribution is predicted following exposure by any physiological route. Furthermore, the overall pattern of toxicity data available suggests that the toxicological effects of ethyl cyanoacrylate would be largely restricted to local site of contact effects on the eyes and respiratory tract." Loctite concurs with these conclusions.

To address concerns that cyanoacrylates, including ethyl cyanoacrylate may act as respiratory sensitizers capable of inducing allergic asthma, Loctite Corporation sponsored two studies. The first was a survey to determine the airborne concentrations of cyanoacrylate in a manufacturing plant<sup>8</sup> and the second was an epidemiological<sup>9</sup> study that investigated the pulmonary effects of repeated occupational exposure to cyanoacrylates. The airborne concentrations determined in the first study provided the basis for the epidemiological study. The epidemiological study provided no evidence that those occupationally exposed to cyanoacrylate vapors during the manufacture and packaging of methyl and ethyl cyanoacrylate adhesives had any chronic pulmonary damage or that ethyl cyanoacrylate acted as a respiratory sensitizer. Subjects who had been exposed for a period of up to 18 years had no increased incidence of pulmonary obstruction compared to an unexposed population.

<sup>&</sup>lt;sup>4</sup> McGee W.A., et al, Am. Ind. Hyg. Assoc J., <u>29</u>, 558-561, 1968.

<sup>&</sup>lt;sup>5</sup> 60 FR 42982-7, 1995

<sup>&</sup>lt;sup>6</sup> NTP 1998 Annual report Table 6.

Methyl Cyanoacrylate and Ethyl Cyanoacrylate, Risk Assessment Document, UK Health and Safety Executive HMSO, Norwich UK, 2000.

<sup>&</sup>lt;sup>8</sup> Paustenbach, D., et al, Am. Ind. Hyg. Assoc J., <u>62</u>, 70-79, 2001.

<sup>&</sup>lt;sup>9</sup> Goodman, M., et al, J. Toxic. & Environ. Hlth Part A, <u>59</u>, 135-163, 2000.